



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2018-0243; FRL-10000-23]

Furilazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of furilazole in or on sweet corn commodities. The Monsanto Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting these tolerances.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2018-0243, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket

available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any

aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2018-0243 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2018-0243, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 18, 2018 (83 FR 52787) (FRL-9984-21), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP IN-11139) by Monsanto, 1300 I Street NW, Washington, DC 20005. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of furilazole when used as an inert ingredient (safener) in pesticide formulations applied to corn, sweet, forage at 0.01 parts per million (ppm); corn, sweet, kernel plus cob with husks removed at 0.01 ppm; and corn, sweet, stover at 0.01 ppm. That document referenced a summary of the petition prepared by Monsanto, the registrant, which is available in the docket, <http://www.regulations.gov>.

Based upon review of the data supporting the petition, EPA is establishing the tolerances as requested.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA

section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for furilazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with furilazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicological profile of furilazole is discussed in the final tolerance rule found in the **Federal Register** of October 10, 2007 (72 FR 57489) (FRL-8145-2). Specific information on the studies received and the nature of the adverse effects caused by furilazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in Unit III.A. of that **Federal Register** document and in the supporting documents for that rule. In addition, due to the similarities between that rule and this, EPA is incorporating the findings concerning the children's safety factor and cumulative exposure into this rule because they also apply to this rulemaking. The summary of toxicological endpoints the Agency used to assess risk are discussed in the final tolerance rule found in the **Federal Register** of April 3, 2002 (67 FR 15727) (FRL-6828-4).

B. Exposure Assessment

1. *Dietary exposure (food and drinking water).* In evaluating dietary exposure to furilazole, EPA considered exposure under the proposed exemption from the requirement of a

tolerance as well as the already established tolerances for furilazole.

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for the general population for furilazole; therefore, a quantitative acute dietary exposure assessment for the general population is unnecessary.

However, such effects were identified for furilazole for females 13 to 50 years old. In estimating acute dietary exposure, EPA used 2003-2008 food consumption information from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted an unrefined acute dietary exposure and risk assessment assuming 100 percent crop treated (PCT), default processing factors, and tolerance-level residues for all food commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA conducted an unrefined chronic dietary exposure and risk assessment assuming 100 PCT, default processing factors (when available), and tolerance level residues for all food commodities.

iii. *Cancer.* As indicated in the 2002 Federal Register document, EPA has concluded that furilazole should be classified as a possible human carcinogen and a linear approach has been used to quantify cancer risk since no mode of action data are available.

The aggregate cancer risk assessment for adults takes into account exposure estimates from dietary consumption of furilazole from food and drinking water sources. Dietary exposure

assessments were quantified using the same estimates as discussed in Unit III.B.1.ii, Chronic Exposure.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for furilazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of furilazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

The estimated drinking water concentrations (EDWCs) of furilazole for acute exposures are estimated to be 1.2 parts per billion (ppb) for surface water and 0.02 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 0.8 ppb for surface water and 0.02 ppb for ground water; and for chronic exposures for cancer assessments are estimated to be 0.22 ppb for surface water and 0.02 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, a water concentration value of 1.2 ppb was used to assess the contribution to drinking water, for the chronic dietary risk assessment, the water concentration value of 0.8 ppb was used to assess the contribution to drinking water. For the cancer dietary risk assessment, the water concentration value of 0.22 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). There are no residential uses of furilazole; therefore, a residential exposure assessment was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to furilazole and any other substances; furilazole does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that furilazole has a common mechanism of toxicity with other substances.

C. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to furilazole will be less than 1% for females 13 to 49 years old, the only population group of concern.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to furilazole from food and water will utilize 13.3% of the cPAD for non-nursing infants, the population group receiving the greatest

exposure. There are no expected residential uses and therefore chronic residential exposure to residues of furilazole is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no proposed or registered residential uses of furilazole a short-term assessment was not performed. The chronic risk assessment is protective for any short-term exposures from food and drinking water.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there are no proposed or registered residential uses of furilazole an intermediate-term assessment was not performed. The chronic risk assessment is protective for any intermediate-term exposures from food and drinking water. Furilazole is not currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that intermediate-term aggregate exposure assessment is not necessary.

5. *Aggregate cancer risk for U.S. population.* A cancer aggregate assessment was conducted for furilazole since it is classified as a “Group C, Possible Human Carcinogen” with a Q^{1*} of $0.0274 \text{ (mg/kg/day)}^{-1}$ based upon hepatocellular adenomas and carcinomas in rats and mice, bronchioalveolar adenomas and carcinomas in female mice, testicular interstitial cell interstitial cell tumors in male rats, and stomach tumors in female mice. The cancer risk estimate for adults is 1.1×10^{-6} .

EPA generally considers cancer risks (expressed as the probability of an increased cancer case) in the range of 1 in 1 million (or 1×10^{-6}) or less to be negligible. The precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of

magnitude on the logarithmic scale; for example, risks falling between 3×10^{-7} and 3×10^{-6} are expressed as risks in the range of 10^{-6} . Considering the precision with which cancer hazard can be estimated, the conservativeness of low-dose linear extrapolation, and the rounding procedure described above, cancer risk should generally not be assumed to exceed the benchmark level of concern of the range of 10^{-6} until the calculated risk exceeds approximately 3×10^{-6} . This is particularly the case where some conservatism is maintained in the exposure assessment. EPA has concluded the cancer risk for all existing furilazole uses and the uses associated with the tolerances established in this action fall within the range of 1×10^{-6} and are thus negligible.

EPA has concluded that using the nonlinear approach based on the chronic RfD will be protective of potential carcinogenicity.

Because the chronic risk is below the Agency's level of concern, EPA concludes there is no aggregate cancer risk from exposure to furilazole.

6. *Determination of safety.* Taking into consideration all available information on furilazole, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to furilazole.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography using electron capture detection) is available to enforce the tolerance exemption expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established any MRLs for furilazole.

C. Response to Comments

Three comments were submitted to the docket for this action. One dealt with “relaxing” current EPA standards; another argued that inert ingredients should be regulated through tolerances. A third comment took issue with data submitted about the toxicity of “Florazole” (which EPA assumes is a typographical error and is meant to apply to furilazole).

This action establishes tolerances for an inert ingredient used as a safener in pesticide products; it is not relaxing EPA standards or ignoring the potential adverse effects of inert ingredients. Inert ingredients are evaluated under the same safety standard as active ingredients under the FFDCA. Under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide chemical tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide chemical meets the safety standard imposed by the statute. EPA has evaluated the potential adverse effects from exposure to this

pesticide chemical, taking into consideration data on the potential for developmental toxicity and carcinogenicity. No new toxicity data were submitted in connection with the present petition.

After evaluating the available data and other information, EPA has determined that the tolerances for this chemical are safe. The commenters have provided no other information for the Agency to consider in making its safety determination.

V. Conclusion

Based on available data, the Agency concludes that tolerances for residues of furilazole as discussed in this document are safe. Accordingly, the Agency is establishing tolerances for residues of furilazole in or on corn, sweet, forage; corn, sweet, kernel plus cob with husks removed; and corn, sweet, stover at 0.01 ppm. In addition, EPA is revising the tolerance expression to clarify that (1) as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of furilazole not specifically mentioned and (2) compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled

“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 17, 2019.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.471(a):

a. Revise the introductory text; and

b. Add alphabetically the entries “Corn, sweet, forage”; “Corn, sweet, kernel plus cob with husks removed”; and “Corn, sweet, stover” to the table.

The revision and additions read as follows:

§ 180.471 Furilazole; tolerances for residues.

(a) *General.* Tolerances are established for residues of furilazole, including its metabolites and degradates, when used as an inert ingredient (safener) in pesticide formulations applied to the following raw agricultural commodities. Compliance with the tolerance levels specified in the table in this paragraph (a) is to be determined by measuring only furilazole, 3-dichloroacetyl-5-(2-furanyl)-2, 2-dimethyloxazolidine (CAS Reg. No. 121776-33-8) in or on the commodity.

Commodity	Parts per million
* * * * *	
Corn, sweet, forage	0.01
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	0.01
* * * * *	

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